UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

OK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/214,881	06/07/99	OZAKI	S 571761PCUS

EXAMINER

HM12/0615

CHRISTOPHER J. BUNTEL, PH.D.
BAKER BOTTS L.L.P.
910 LOUISIANA
HOUSTON TX 77002

NOLAN, P

ART UNIT	PAPER NUMBER
1644	15

DATE MAILED:
06/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/214,881	Ozaki et al.
Examiner	**Art Unit**
Patrick Nolan	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 4, 2000* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *4, 6, 7, and 9-13* is/are pending in the application.

4a) Of the above, claim(s) *7 and 9-13* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *4 and 6* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Part III DETAILED ACTION

1. Claims 4, 6-7 and 9-13 are pending.

2. The request filed on 5-29-01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/214,881 is acceptable and a CPA has been established. An action on the CPA follows.

3. Claims 7 and 9-13 and stand withdrawn from consideration as being directed to a non-elected invention, for reasons set forth in Paper No. 11.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of human, porcine, bovine and rat HMG for the binding of autoantibodies in human SLE, Sjogrens syndrome, Behcet's disease, scleroderma, primary biliary cirrhosis, microscopic polyangitis/polyarteritis nodosa, ulcerative colitis, Crohn's disease and autoimmune hepatitis does not reasonably provide enablement for the use of any HMG-1 or HMG-2 family protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Colman et al. (U), teaches that single amino acid changes in antigen can abolish the antibody-antigen interaction entirely, providing an effective mechanism for antigenic variation (page 33, in particular). Therefore since applicant's claims read on changing the HMG-1 or HMG-2 protein by 90% or 80% derivatives, it is unpredictable what type of antigen will result, and more importantly whether or not said autoantibodies in the disease states will be effective bound to diagnose the selected diseases. The specification does not adequately describe what would be meant by the 80% homologous or 90% homologous, there is no clear identification of which amino acids would be changed by mutating the HMG-1 and HMG-2 polypeptides and how they would effect the autoantibody binding activity of the encoded polypeptide.

Since, Applicant has provided no working examples of 80% or 90% homologues of HMG-2 and HMG-1 respectively, which bind autoantibodies in the diseases set forth above, and the state of

the art as taught by Colman et al., teaches that single amino acid changes create unique and distinct epitopes which usually won't bind the original antibody prior to its change, the practice of the breadth Applicant`s invention would require an undue amount of experimentation for one of skill in the art to practice.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 4 and 6 are rejected under 35 U.S.C. § 103 as being unpatentable over Ayer et al. (V).

Ayer et al., teaches the bovine HMG-1 and the HMG-2 proteins (Figure 1 in particular), and the use of said proteins in the detection of autoantibodies to Scleroderma (Figure 2 and 3, in particular), wherein said autoantibodies are detected by secondary antibodies or I^{125}-protein A (Figure 2 and 3 in particular).

The claimed invention differs from the prior art teaching(s) only by the recitation of placing said HMG-1 or HMG-2 proteins taught by Ayer et al., in a kit. However, one skilled in the art would have recognized the usefulness of supplying an antibody test kit for use in diagnostic assays. Test kits are compounds packaged for the convenience of the practitioner and are conventionally made to reproducibly obtain results under test conditions and it is

conventional to assemble all necessary reagents, including antibodies, buffers and standards for the convenience of the practitioner and commercial expediency. Furthermore, the preamble reciting "A kit for ..." does not convey any patentable weight to the actual components of the kit itself.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to assay for the presence of autoantibodies in scleroderma against HMG-1 and/or HMG-2 as taught by Ayer et al., and package the assay as a kit with the expectation that kits allow for ease and commercial reproducibility of known assays.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

6. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
June 14, 2001